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| APPLICATION NO.                               | FILING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/705,673                                    | . 11/10/2003 | Satoshi Mizutani     | 20050/0200473-US0   | 4666             |
| 7278 7590 07/12/2007<br>DARBY & DARBY P.C.    |              | EXAMINER             |                     |                  |
| P.O. BOX 770                                  |              |                      | REICHLE, KARIN M    |                  |
| Church Street Station New York, NY 10008-0770 |              |                      | ART UNIT            | PAPER NUMBER     |
| New Tork, NT                                  | 10000-0770   |                      | 3761                | <u> </u>         |
|   |              |                      |                     |                  |
|   |              |                      | MAIL DATE           | DELIVERY MODE    |
|   |              |                      | 07/12/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|   |   | Application No.   | Applicant(s)    |  |  |  |
|---|---|---|-----------------|--|--|--|
| . Office Action Summary   |   | 10/705,673  | MIZUTANI ET AL. |  |  |  |
|   |   | Examiner  | Art Unit        |  |  |  |
|   |   | Karin M. Reichle  | 3761            |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |   |                 |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |   |                 |  |  |  |
| Status  |   | ,   |                 |  |  |  |
| 1) Responsive to com  | nmunication(s) filed on 25  | <u>April 2007</u> .   |                 |  |  |  |
| 2a)⊠ This action is FINA  | This action is FINAL. 2b) ☐ This action is non-final.   |   |                 |  |  |  |
| <i>'</i> — ···  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |   |                 |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |   |   |                 |  |  |  |
| Disposition of Claims   |   |   |                 |  |  |  |
| <ul> <li>4)  Claim(s) 1 and 4-32 is/are pending in the application.</li> <li>4a) Of the above claim(s) 4-18,21-27,29 and 31 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1,19,20,28,30 and 32 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> </ul>   |   |   |                 |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |   |                 |  |  |  |
| Application Papers  | abjected to by the Evemin   |   |                 |  |  |  |
| 9)⊠ The specification is objected to by the Examiner.  10)⊠ The drawing(s) filed on <u>13 November 2006</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.  |   |   |                 |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |   |                 |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |   |                 |  |  |  |
| Priority under 35 U.S.C. § 119  |   |   |                 |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |   |                 |  |  |  |
| Attachment(s)  1) Notice of References Cited (legal parts)  Notice of Draftsperson's Pate 3) Information Disclosure State Paper No(s)/Mail Date   | ent Drawing Review (PTO-948)<br>ment(s) (PTO/SB/08)   | 4) Interview Summal<br>Paper No(s)/Mail (<br>5) Notice of Informal<br>6) Other: | Date            |  |  |  |

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#### **DETAILED ACTION**

#### Election/Restrictions

1. Claims 4-18, 21-27, 29 and 31 are still withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 7-7-05. The layer configuration species of Figure 43, the pad and inner wrapping configuration species of Figure 6A, the outer wrapping configuration species of Figure 22, and the outer package configuration species of Figure 51 were elected. New claim 31 requires the minisheet piece be formed of a film which is corrugated which is not shown in the elected species of the Figures set forth supra. Therefore, Applicant's 4-30-07 remarks are deemed not persuasive.

## Response to Amendment

2. The substitute specification filed 11-13-06 still does not comply with 37 CFR 1.121, e.g. compare page 29, line 17 of the marked up copy of 11-13-06 and page 33, line 20 of the original specification. Note also paragraph 7, section 7 of the 8-6-05 Office Action. The amendments to the abstract still do not comply with 37 CFR 1.121, i.e. the text of the second paragraph of the abstract deleted is not that of the original, i.e. where are the numerals shown in the original shown as deleted. However such have been entered. Therefore the following action is based on the substitute specification and abstract filed 11-13-06, and as amended 4-25-07, the Figures filed originally and 11-13-06 and the claims filed 4-25-07.

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# Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

For Example:

## **Drawings**

- 4. The drawings were received on 4-25-07. These drawings are not approved by the Examiner. Figure 28 as proposed includes two lines of adhesive 16 at two locations. Where is the support for such as originally filed? Applicant has not set forth the portion of the specification relied upon for such. Note MPEP 714.02, second to last paragraph. Therefore see the following paragraph.
- 5. The drawings are objected to because in Figure 28, the adhesive, see page 40, last two lines, should still be denoted. The Figures and descriptions thereof throughout the specification should be carefully reviewed and revised, as necessary, to provide a consistent description both pictorially and textually. Applicant is thanked in advance for his/her assistance in placing the specification in consistent form. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the

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remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

# Description

- 6. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the abstract, last sentence.
- 7. The disclosure is objected to because of the following informalities: The specification is replete with informalities. For example: 1) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims is still not commensurate in scope, see MPEP 608.01(d). 2) Is the broken line 15 only provided in the rear face of the wrapping container? If so, how is the front face of the wrapping container divided as shown in Figure 7? It should be noted that the front face of the wrapping container is believed to be as shown in Figures 1(D) or 3(B), i.e. how is tape 14 and sealed longitudinal ends on the front end torn? 3) It is also not unclear how the various "implementations" set forth in the portion of the

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Summary of the Invention section that has been relocated after the subtitle Detailed Description of the Invention, other than those that specifically refer to a specific Figure, relate to the descriptions of the various embodiments which follow. 4) The portions of the relocated text referred to in 3) which clearly set forth certain Figures should be relocated to those portions of the description discussing those Figures. The specification should be carefully reviewed and revised, as necessary, to overcome all the informalities. Applicant is thanked in advance for the cooperation in placing the specification in proper form. See also the Response to Arguments section infra.

Appropriate correction is required.

# Claim Objections

- 8. Claims 1, 19-20, 28, 30 and 32 are objected to because of the following informalities: In claim 1, line 6, "a" should be deleted. On line 9, "to a" should be --in a--. Appropriate correction is required.
- 9. Applicant is advised that should claim 1 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

As best understood, see the discussion in paragraph 11 infra, lines 4-8 of claim 1 sets forth the same thing as claim 28.

# Claim Rejections - 35 USC § 112

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10. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written rejection. The language should focus on those factors reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in claim 30 the invention is a minisheet of material having a breaking strength of 0.6 to 2.5 N/inch lateral. Therefore, the claim also defines the invention by the tests or processes used to determine the breaking strength.

In the instant application, no test, standardized or not has been disclosed with regard to measurement of the breaking strength, i.e. no method, no equipment. Nor is there a specific example of such a material. In other words, the test used to measure the claimed physical characteristic is not described or disclosed, i.e. enabled, and thus, the claim relying on such is not enabled. Experimentation to determine whether a particular material might include the claim

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limitation would entail, e.g., all known possible tests, standardized or not, which yield a measurement having the units N/inch lateral, i.e. undue experimentation.

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

11. Claims 1, 19-20, 28, 30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, the invention which is claimed on lines 4 et seq is unclear, e.g. how many finger insertion portions is applicant claiming? One on line 6 or two on lines 7-8? Are the mini sheet pieces attached only to the separate sections, i.e. after the wrapping sheet is divided, or are they connected to the wrapping sheet prior to division, i.e. each piece is attached to one of the two separable sections rather than the two separate sections? What structure is being set forth on lines 9-10, i.e. what is for inserting and passing a finger therethrough? The direction? An opening? Each mini sheet? See also the discussion in paragraph 8 supra. Also, note dependent claims 28, 30 and 32. A clear description should be set forth. See paragraph 12 infra. In claim 30, a positive structural antecedent basis for "the mini sheet piece", i.e. there is more than one sheet piece claimed in claim 1, should be set forth.

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# Claim Language Interpretation

12. The claim terminology is interpreted in light of the specific definitions in the paragraph bridging pages 25-26. Any other claim language not specifically defined has been interpreted in view of the usual and common meaning of such, i.e. the dictionary definition. Also, as best understood, the terminology "wrapping body" refers to the combination of the wrapping container and the pad, and the "wrapping container" is the finished product of "wrapping sheet" without the pad. Therefore it is also noted that claims 1, 19-20, 28, 30 and 32 also do not require an interlabial pad merely the capability of individually wrapping such and the capability of inserting or removing such. The terminology "mini sheet piece" is interpreted to require a piece which is a sheet of a size smaller than some other structure of the container. With regard to claim 1, as best understood, see paragraph 11 supra, and thereby also claim 28, see discussion in paragraph 9 supra, a wrapping sheet with a broken line and finger insertion portions for each separable section wherein each separable section is provided for inserting or removing a pad with a finger inserted into the finger insertion portion thereof to do so, i.e. open in a direction for inserting and passing a finger, is interpreted to be required. With regard to claim 30, in light of the discussion supra in paragraphs 10-11, i.e. no specific test used to determine such set forth and lack of antecedent basis for "the mini sheet piece", a material which does not tear or become damaged during normal use unless desired, i.e. broken along the broken line, i.e. see the original specification at page 60, lines 18-20 and the claims, will be considered to meet this claim. With regard to claim 32, it is noted that this claim only requires each mini sheet piece attachment at some point being at equal and opposing distances from the broken line.

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# Claim Rejections - 35 USC § 102

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 1, 19-20, 28, 30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Fitz '911.

Claims 1 and 28: See Claim Language Interpretation section supra and Fitz '911 at the Figures, especially Figures 2a-2e and 4-7, and col. 1, lines 42-55, col. 2, line 21-col. 3, line 24, col. 3, line 62-63, col. 4, line 42-col. 5, line 37, the last paragraph of col. 5, the first paragraph of col. 6, col. 6, line 28-col. 8, line 57, e.g. the container is H1-H5, the wrapping sheet is the container H1-H5 without the feminine hygiene article or tampon and the broken line of perforations is 50 or 51, see the first full paragraph of col. 3, which enables the wrapping sheet to completely separate or divide into two separate sections, e.g. 10 and 20, as best understood, see the Claim Language Interpretation section supra again (i.e. finger insertion portions for each separable section wherein each separable section is provided for inserting or removing a pad with a finger inserted into the finger insertion portion thereof, i.e. open in a direction for inserting and passing a finger, required), each separable section of '911 has a finger insertion portion, e.g. the space within each section which receives the finger, and the fingers are inserted into each finger insertion portion of each separate section to insert or remove the feminine hygiene article. The minisheets of the separable sections are the respective portions on either side of the broken line of one of the two planar portions of film disclosed at col. 5, lines 62-col. 6, line 7 which portions are attached at their side edges to the other of the two planar portions of film. The claims further require the container having the capability for individually wrapping an interlabial pad and the

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sections and finger insertion portions enabling insertion and removal of such a pad. However, it is the Examiner's first position that the tampon as disclosed by Fitz '911 is an "interlabial" pad in that it is inserted between the labia and thereby, the '911 reference explicitly teaches such capabilities. In any case, i.e. the Examiner's second position, '911 teaches all the claimed structure and the capability of using such structure similarly to that claimed for a feminine hygiene absorbent article of similar size and for use in a similar environment. Therefore, there is sufficient factual evidence for one to conclude that the capabilities of such claimed structure would also be inherent in the same structure of '911, see MPEP 2112.01.

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Claim 19: See Figure 4, elements 70 and 71 and col. 4, line 52-col. 5, line 5, i.e. the container includes a laminate material having a fiber sheet 70, 71 on an inner face and a plastic film sheet on an outer face.

Claim 20: See, e.g., claim 25 of '911.

Claim 30: See Claim Language Interpretation section supra and, e.g., col. 2, lines 35-46, the paragraph bridging cols. 2-3, col. 5, first full paragraph and col. 5, lines 52-55 of '911, i.e. a material which does not torn or damaged during normal use unless desired, i.e. broken along the broken line. Therefore, the '911 reference is deemed to include a material as claimed as best understood.

Claim 32: See the Claim Language Interpretation section supra and '911, i.e. the minisheets of the separable sections are the respective portions on either side of the broken line of one of the two planar portions of film disclosed at col. 5, lines 62-col. 6, line 7 which portions are attached at some point at their side edges to the other of the two planar portions of film at

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equal and opposing distances from the broken line, see, e.g., directly adjacent, i.e. above and below, the rightmost and leftmost ends of broken line 50 as shown in Figure 7.

## Response to Arguments

either deemed moot in that they have not been reraised or deemed not persuasive for the reasons discussed supra. Specifically with regard to Applicant's remarks on page 31, second full paragraph, where is such description of broken line 15 and the opening of the front face and such at the same time to remove the pad set forth. Figures 7A-C do not show such. With regard to Applicant's remarks on page 32, second full paragraph have also been noted but the specification does not disclose which tests are considered "suitable" regardless of whether such tests are well-known or not. The remarks with regard to the prior art have been considered but are deemed not persuasive in light of the discussion in the discussion supra, i.e. narrower than the structure clearly claimed in the claims and the structure taught by the prior art.

## Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to the claims 1 and 30 and the addition of claim 32.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karin M. Reichle Primary Examiner Art Unit 3761

KMR June 28, 2007